REMARKS

Claims 50-54, 83-97 and 99-108 are pending. Claims 83-97 and 99-108 are rejected and claims 50-54 are withdrawn from consideration.

With this amendment independent claims 83 and 104 and dependent claims 84-90, 94, 96, and 97 are amended, no new claims are added, and no claims have been cancelled. Applicants aver that no New Matter is entered hereby.

Applicants have reviewed the Office action, including the Examiner's remarks and the references cited therein. Applicants submit that the following remarks are fully responsive to the final Office action, and that all pending claims are patentable over the cited references.

Request for Reconsideration

Applicants respectfully request that the finality of the Office action be rescinded for several reasons not the least of which is that the narrative provided with the Office action was nearly devoid of any detailed analysis of the claimed invention *and the applied references* thereby making it unclear which portions of which claim and which portion of which reference the Examiner relied upon.

Applicants direct attention to Page 5 of the final Office action wherein nearly all pending claims are summarily rejected as allegedly anticipated – with a single sentence for each of the two references. One reference, to Choy, is only a few pages long while the other to Edwards is on the order of dozens of pages long. Regardless, Applicants deserve to be placed on reasonable notice as to the specific rejections so they can accurately and precisely respond.

Applicants suggest that, on its face, the *rejections posited* wholly fail to meet even the minimum requirements for a rejection grounded in anticipation as *each and*

every element must be shown to be disclosed, expressly or via principles of inherency, or the rejection must be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 83, 89, 90, 94 and 97 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Choy (US 4,207,874).

Claims 83-89, 94, 96, 97 and 99-101 stand rejected under 35 U.S.C. §102(e) as being anticipated by Edwards, et al. (US 6,325,798).

Section 102(b) provides that "[a] person shall be entitled to a patent unless . . . the invention was . . . described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). To qualify as a printed publication, the Professional Protein ad must have been disseminated or otherwise made accessible to persons interested and ordinarily skilled in the subject matter... prior to the critical date. To be anticipatory, the [*content*] of a printed publication must also describe, either expressly or inherently, ***each and every claim limitation and enable*** one of skill in the art to practice an embodiment of the claimed invention without undue experimentation. In re Gleave, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (***emphasis added***).

With respect to Choy: Choy fails to anticipate the claimed invention as previously, and particularly as herein amended, because Choy does not disclose or deal with the subject matter claimed. That is Choy deals with clearing *thrombus* obstructions from "a tube" (e.g., blood vessels) and it not disputed that *thrombus* does not constitute *epicardial tissue* (or even tissue, for that matter). To wit: **a clot of blood formed within a blood vessel** and remaining attached to its place of origin (**emphasis added** - source: Merriam-Webster's Medical Dictionary 2002). Applicants assert that the Examiner's restated rejection(s) put forth in the instant final Office action in an non-annotated narrative is not persuasive as the claims previously presented affirmatively stated that the device "temporarily mechanically couple to a *tissue surface.*" Since

Choy fails to disclose each and every claim element and recited limitation the rejection based solely upon Choy should be withdrawn. Applicants request that the rejection of claims 83, 89, 90, 94, and 97 be withdrawn as failing to meet the required threshold for a proper anticipation rejection.

With respect to Edwards: Edwards likewise deals with removal of non-tissue material disposed in a vessel and the devices and methods therein would not work and would like cause AEs if deployed into the pericardial space of the heart of a subject. At the least the devices would not provide for any relief from a cardiac arrhythmia for the subject. Importantly, Edwards does not disclose *each and every* claim element and limitation recited in the amended claims and should be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 84-88, 91-93 and 95 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Choy.

Claims 90-93, 95, 102, 103 and 105-108 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Edwards.

With respect to Choy: The remarks regarding Choy presented above are incorporated herein and applicants strongly suggest that Choy, standing alone, wholly fails to provide a basis for an obviousness rejection of the claimed invention, and certainly fail to reach the required threshold of a *prima facie* obviousness rejection.

With respect to Edwards: The remarks regarding Edwards presented above are incorporated herein and applicants strongly suggest that Edwards, standing alone, wholly fails to provide a basis for an obviousness rejection of the claimed invention, and certainly fail to reach the required threshold of a *prima facie* obviousness rejection. Some select excerpts from Edwards (below) should assist the Examiner in appreciating the (patentable) differences between the claimed invention and Edwards (highlighted for

emphasis). In sum the rejection based solely upon Edwards fails to render the claimed invention obvious and should be withdrawn

Edwards '798 excerpts:

Abstract

Systems and methods treat a tissue region at or near a sphincter by deploying a carrier, which carries an electrode that can be advanced to penetrate tissue. Negative pressure is applied through a suction port on the carrier near the electrode, to draw tissue in the tissue region inward against the carrier. The systems and methods advance the electrode to penetrate tissue drawn against the carrier. The vacuum anchors the surrounding tissue and mediates against the "tenting" of tissue during electrode penetration. Without tenting, the electrode penetrates mucosal tissue fully, to obtain a desired depth of penetration.

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The invention provides systems and methods for treating a tissue region at or near a sphincter. The systems and methods deploy a carrier in the tissue region. The carrier carries an electrode that can be advanced to penetrate tissue. The systems and methods apply negative pressure through a suction port on the carrier near the electrode to draw tissue in the tissue region inward against the carrier. The systems and methods advance the electrode to penetrate tissue drawn against the carrier.

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The electrodes 264 have sufficient distal sharpness and strength to penetrate a desired depth into the smooth muscle of the esophageal or cardia 20 apply energy from the generator 38.

Applying a vacuum to draw mucosal tissue inward against the pods 256 causes the tissue to present a surface nearly perpendicular to the electrode ports 262 (see FIG. 69). Operation of the driver disk 254 moves the electrodes 264 through the ports 262, in a direct path through mucosal tissue and into the underlying sphincter muscle. Due to the direct, essentially perpendicular angle of pentration, the electrode 264 reaches the desired depth in a short distance (e.g., less than 3 mm), minimizing the amount of

insulating material 278 required.

The application of vacuum to draw mucosal tissue against the pods 256 also prevents movement of the esophagus while the electrodes 264 penetrate tissue. The counter force of the vacuum resists tissue movement in the direction of electrode penetration. The vacuum anchors the surrounding tissue and mediates against the "tenting" of tissue during electrode penetration. Without tenting, the electrode 264 penetrates mucosal tissue fully, to obtain a desired depth of penetration.

Double Patenting Rejections

Claims 83-97 and 99-11 are provisionally rejected on the grounds of non-statutory, obviousness-type double patenting over claims 1-11 of United States Patent No. 6,161,543.

Claims 83-97 and 99-108 are provisionally rejected on the grounds of non-statutory, obviousness-type double patenting over claims 1-49 of United States Patent No. 6,237,605.

Claims 83-97 and 99-108 are provisionally rejected on the grounds of non-statutory, obviousness-type double patenting over claims 1-25 of United States Application No. 11/882,072.

Claims 83-97 and 99-108 are provisionally rejected on the grounds of non-statutory, obviousness-type double patenting over claims 1-31 of United States Application No. 11/646,524.

Claims 83-97 and 99-108 are provisionally rejected on the grounds of non-statutory, obviousness-type double patenting over claims 1-21 of United States Application No. 11/878,375.

Applicants respectfully disagree but will be mindful of the provisional rejection as prosecution proceeds so that the rejection can be later traversed based on a fair interpretation of the scope and breadth of any actually allowed claims. Of course, Applicants reserve the right to file one or more terminal disclaimers in the event the Examiner is not persuaded that this ground of rejection cannot be successfully

traversed. However, in view of the amendments and Remarks presented herein it appears as though the subject matter claimed at least facially appears to diverge from the claims of the co-pending application cited hereinabove.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that the application is in condition for allowance, and request that all rejections be withdrawn, that all pending claims be allowed, and that the application be passed to issue. If, for any reason, the Examiner finds the application to be in other than condition for allowance, the Examiner is invited to contact the undersigned in an effort to resolve any matter still outstanding before issuing another action.

Respectfully submitted this 13th day of January 2010.

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